

## **REMARKS**

Pending claims 18, 19 and 33 have been amended. Claims 1-17, 22, 24, 26, 27, 30, 37 and 38 have been canceled. New claims 40 and 41 have been added.

### **May 17, 2006 Interview**

Applicant's attorney thanks Examiner Bunin and PE Mitchell for the opportunity to discuss the pending claims, in particular amended claim 18 and new claim 40.

Examiner Mitchell and Examiner Bunin advised Applicant's attorney that a neutral centric position does not provide any structural difference than the apparatus of Goldstein. Further, they report Applicant's attorney stated the substantially neutral centric position is achieved through trial and error of making the device. This is not technically correct. Dental impressions are taken of the upper and lower set of teeth and then a dual arch oral appliance is made taking into account the patient's bite registration. It is possible that trial and error is necessary if the oral appliance is not made correctly the first time. Applicant's attorney regrets any misunderstanding conveyed to Examiners Bunin and Mitchell.

No agreement as to patentability was reached.

### **Independent claim 18**

The Examiner has rejected independent claim 18 as being unpatentable under 35 U.S.C. 103(a).

As will be discussed below, the Examiner misconstrued the function of parts 122 and 202/204 of the '455 patent. Claim 18 has also been amended to further clarify the distinction.

First, the Examiner states that Goldstein has an anterior, extraoral slide 122 or 202/204...capable of maintaining the patient's mandible in a substantially neutral centric position without protrusion of the mandible. This is incorrect.

Part 122 refers to a spreader (Col.5, lines 49-61& Fig. 17) the purpose of which is to cause the upper outlet portions of the tubes 118 and 120 to be stressed away from each other. Part 202/204 refer to a pair of bosses (Col. 6, lines 64-67 & Fig. 23) the purpose of which is to pivot tubes 206 and 208 about pivot pin 210.

By contrast, the tubing retention platform disclosed in claim 18 is capable of sliding along the extraoral slide. (Spec. page 9, lines 26-30). In other words, the slide extends away from the dual arch oral appliance (as shown in Fig. 1) and the tubing retention platform, once slidably mounted upon the slide, can be displaced along the slide to a desired position. The parts referred to by the Examiner in the Goldstein reference do not allow the tubing retention platform to displace towards, or away from the dual arch oral appliance.

Nevertheless, Applicant acknowledges that U.S. Pat. No. 6,571,798 issued to Thornton, teaches an extended arm 22 coupled to the mouthpiece section (see Fig. 1), and that a CPAP interface 44 having nasal pillows 30 extending therefrom (see Fig. 3), can be coupled to extended arm 22 (Col. 8, lines 4-8).

#### Obturation Argument

Neither Thornton, nor Goldstein, teach or suggest obturation of the oral cavity using a dual arch oral appliance and providing a neutral centric position for the patient's mandibular and maxillary arches. Thornton '798 discloses the use of either a venting seal 24 or mask 60 (see Fig. 1 and Fig. 4). Goldstein '510 discloses holes 29 in the mouthpiece to permit breathing

through the user's mouth. (Col. 5, lines 2-4 & Fig. 2). Goldstein '455 does not teach obturation of the oral cavity nor maintaining the patient's jaw in a neutral centric position. Goldstein '455 is only concerned with utilizing the mouthpiece as a dental anchor that supports a nasal air delivery apparatus. (Col. 1, lines 52-55).

Further, Goldstein '455 is a continuation-in-part of Serial No. 08/749,228, now U.S. Pat. No. 5,752,510. Goldstein '510 states that an object of the invention resides in an air delivery system that "anchors or stabilizes the system from a mouthpiece and the user's chin." (Col. 2, lines 45-48)(emphasis added). Goldstein '455 refers to the mouthpiece as a "dental anchor" but does not teach that the anchor can be used to obturate the oral cavity or maintain the jaw structure in a neutral centric position.

The dental anchor 24 of Goldstein '455 (Fig. 1 and 3) is similar to the oral appliance 10 of Thornton '798. The only difference is that Thornton '798 begins with separate arches 12 and 14 which are then bonded together with deformable material 16 (Col. 5, lines 37-59). Separate arches allows the invention of Thornton '798 to adjust the relative positions of arches 12 and 14, preferably fixing the forward position of lower arch 14 relative to upper arch 12 (Col. 6, lines 2-4). The ability of Thornton '798 to incrementally adjust the relative positions is why Dr. Jeppesen stated in his declaration that Thornton's orthodic is one of the best instruments for precisely dilating the upper airway mechanically. (Jeppesen Dec. ¶16).

The oral appliance of Thornton '798 is of the same configuration as Goldstein '455, yet Thornton '798 teaches the use of venting seal 24 to substantially eliminate venting of air from the user's mouth when the device is in use.(Col. 6, lines 45-47). Dr. Jeppesen submits that the dental anchor of Goldstein '455 can not obturate the oral cavity in view of Thornton's need for a vent seal. (Jeppesen Dec. ¶17).

### Neutral Centric Position Argument

Goldstein '510 teaches away from using a neutral centric position for the jaw structure. The "Summary of the Invention" discloses that a primary object of the invention is to maintain the user's lower jaw in a forward position. (Col. 2, lines 40-44). Also, Thornton '798 teaches fixing the lower arch forward of the upper. (Col. 6, lines 2-4).

This is in contrast to the neutral centric position of Applicant's invention.

The term "neutral centric position" is found in various places in the specification.

"The bite registration position may be captured either: a) In *neutral centric position*, i.e. without mandibular protrusion/advancement;...". Page 5, lines 20-25;

"The present invention solves this problem by placing the patient's lower jaw in a *neutral centric position* to minimize or eliminate orthodontic forces on the teeth where there is clinical indication to do so." Page 8, lines 19-21;

"The preferred embodiment utilizes a neuromuscular TENS (Transcutaneous Electrical Nerve Stimulation) technique whereby the masticatory muscles are profoundly relaxed to proper working lengths via this pulsing technique placing the mandible in three dimensional harmonious space position with respect to the maxilla. In this manner the mandibular position antero-posteriorly (AP) and vertically is determined by the muscles themselves rather setting an arbitrary position. This neuromuscularly-determined position is referred to earlier in the specification as "*neutral centric position*". If the need presents, due to excessive therapeutic PAP requirements for an individual patient, the AP position of the mandible may be somewhat protruded forward so as to create some mechanical dilation of the upper airway. However, this forward positioning of the mandible will increase the risk of a deleterious change in the patient's occlusion or bite. Therefore, the preferred position will typically be the neutral centric position as determined by the experienced clinician." Page 14, line 23 to Page 15, line 6.

In his declaration, Dr. Jeppesen describes that finding a patient's neutral centric position requires a method to profoundly relax the muscles of mastication which postures the mandible. The temporo-mandibular joint allows the mandible to move like an airplane with pitch, yaw, and roll. (Jeppesen Dec. ¶13). It is therefore not possible for a standard mouthpiece to be used which will provide patients with a neutral centric position. A dental impression and a bite registration

are required from each patient in order to ascertain the neutral centric position; something which Goldstein does not discuss for manufacture of its mouthpiece or dental anchor.

Also, mandibular advancement devices (MAD), can lead to can cause serious injury to the tempor-mandibular joint resulting in all sorts of pathology such as muscle spasm, disk displacement, pain, stiffness, and migraine headaches. (Jeppesen Dec. ¶10). Dr. Jeppesen personally evidenced mandibular advancement cases showing clear detrimental occlusal changes produced by these MAD devices such as proclination of lower anterior teeth and retroinclination of upper anterior teeth, significant changes in the plane of occlusion including both extrusion and intrusion of molar and premolar teeth which resulted in change in vertical dimension of occlusion and permanent advancement of the mandible of 2-7 mm. (Jeppesen Dec. ¶9). This is why Dr. Jeppesen's method of treating chronic sleep apnea is an improvement over prior art methods; not only is chronic sleep apnea successfully treated, it is done so without producing a detrimental condition to the patient's occlusion or bite.

Claim 18 has been amended and is believed to overcome the cited prior art. The claim elements of: a) fabricating a dual arch oral appliance to obturate the oral cavity; b) to substantially prevent venting of air through the oral cavity; and, c) using the oral appliance to maintain the mandibular and maxillary arches in a neutral centric position is not taught by the prior art.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. MPEP §2141.02 citing *Stratoflex, Inc. v.*

*Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983).

Dr. Jeppesen further states (Jeppesen Dec. ¶21) he is unaware of anyone who has:

1) fabricated a dual arch oral appliance to maintain the upper and lower dental arches in the neutral centric position when treating obstructive sleep apnea. The mindset of the typical dental sleep medicine practitioner has been of a single focus, replete with the concept of advancing or protruding the mandible to in order to achieve a mechanical dilation of the upper airway; and,

2) fabricated a single-piece oral appliance to substantially prevent the venting of air from the oral cavity during positive airway pressure treatment via the nasal passages.

Objective evidence of non-obviousness includes commercial success, long felt but unresolved need, failure of others, and copying. *Custom Accessories Inc. v. Jeffrey-Allan Industries Inc.*, 807 F.2d 955; 1 U.S.P.Q.2d 1196 (Fed Cir. 1986).

In his declaration, Dr. Jeppesen states that he is the last resort for many patients; patients referred to him by other treating physicians. (Jeppesen Dec. ¶21). Dr. Jeppesen's commercial success is not based upon marketing or advertising; rather, it is based upon the clinical fact that he has been able to successfully treat an unusually high percentage of acknowledged failure cases using his novel method of treatment.

The clinical data submitted with his declaration documents over 90% of the 52 patients treated successfully. Further, 25 of these 52 patients, patients who were considered established failures of standard therapy, exhibited significant improvement as evidenced by nocturnal polysomnogram examination. (Jeppesen Dec. ¶20).

Attached to Dr. Jeppesen's declaration is a table evidencing the success of his treatment method. Dr. Jeppesen defines a positive outcome as either: a) a minimum 70% improvement over the original respiratory disturbance index (RDI), defined as the average number of respiratory disturbances observed per hour; or, b) less than 5 respiratory disturbance events per hour. (Jeppesen Dec. ¶19). Dr. Jeppesen's success rate is indicative of the failure of others.

This recognized failure of others to successfully treat patients suffering from chronic sleep apnea is further noted by the fact that Dr. Jeppesen regularly receives referrals from board-certified sleep physicians who have been unable to treat their most difficult patients suffering from sleep apnea using conventional positive airway pressure therapy techniques. (Jeppesen Dec. ¶19)

Many patents have issued for methods and devices for correction of sleep apnea further evidencing a long felt but unresolved need. However, Dr. Jeppesen states that the methods and devices which are the subject of these patents are unsuccessful for treatment of chronic sleep apnea.

Finally and most important, the pending claims describe the techniques that Dr. Jeppesen utilizes, and these techniques have led to unparalleled treatment success not described in other patents nor in clinical journals. "A prima facie case of nexus is generally made out when the patentee shows both that there is a commercial success, and that the thing (product or method) that is commercially successful is the invention that is disclosed and claimed in the patent." *Chemical Separation Technology Inc. v. United States*, 51 Fed. Cl. 771; 63 U.S.P.Q.2d 1114, 1140 (US Ct. Fed. Cl. 2002).

Given Dr. Jeppesen's declaration and Goldstein's emphasis on forward mandibular positioning and venting of air through the oral cavity, Applicant submits it would not be obvious

to use the Goldstein references for designing a dual arch oral appliance to position the jaw in a neutral centric position and obturate the oral cavity. In fact, Goldstein's dual arch oral appliance is an inappropriate and pre-determined barrier to achieving a predictable neutral centric position because it will limit the free movement of the mandible that is requisite when attempting to locate the all important neutral centric position.

Dependent claims 19-21, 23, 25, 28-29, 31 and 32 should be in a condition for allowance without amendment.

### **Independent claim 33**

Claim 33 includes the following claim element:

"said dual arch oral appliance fabricated from dental impressions taken of the patient's upper and lower teeth and where said oral appliance is fabricated to maintain the patient's mandibular and maxillary arches in a neutral centric position and designed to substantially obturate the patient's oral cavity".

For the same reasons as expressed earlier for independent claim 18, claim 33 as amended, is believed to avoid the references cited by the Examiner.

As stated earlier for independent claim 18, the claim elements of: a) providing a dual arch oral appliance to obturate the oral cavity; b) to substantially prevent venting of air through the oral cavity; and, c) using the oral appliance to maintain the mandibular and maxillary arches in a neutral centric position is not taught by the prior art.

Applicant believes the Goldstein reference can not be used as a basis to reject claim 33. Accordingly, dependent claims 34-36 and 39 should be in a condition for allowance without amendment.

### **Independent claim 40**



Claim 40 is similar to claim 33 except that it includes the additional limitation of:

"obtaining from the patient a three-dimensional bite registration where the patient's mandibular arch and maxillary arch are in a neutral centric position by relaxing the patient's facial muscles using Transcutaneous Electrical Nerve Stimulation (TENS).

Support for this claim element is found in the specification at page 14, line 23 to page 15, line 6.

**Katz et al. reference (US2004/0115139)**

The Examiner has cited the Katz et al. reference to reject pending claims 32 and 36. Since new claim 40 also includes the subject matter of claims 32 and 36, i.e. using TENS to obtain a three-dimensional bite registration, the following argument will apply to claims 40, 32 and 36.

Attached is Attorney Ralph D. Chabot's Declaration under Rule 1.132. This declaration declares that the Katz et al. reference, printed patent publication US2004/0115139, was published June 17, 2004 on utility application 10/685,986 filed October 15, 2003 that claimed priority to provisional application 60/418,789 filed October 15, 2002.

The filing date of the pending application, July 29, 2003, predates the filing of 10/685,986. Therefore, for Katz et al. to be properly cited by the Examiner as a reference, the subject matter in question, i.e. obtaining a three-dimensional bite registration in a neutral centric position via TENS (found in the publication at paragraphs 142-146), must be disclosed in the earlier provisional application and it is not.

Attached to Attorney Chabot's declaration is a copy of provisional application 60/418,789 obtained from the USPTO PAIR website. The '789 application does not in any way

disclose or mention the use of TENS and therefore, there is an absence of an enabling disclosure with respect to the use of TENS. Applicant submits that Katz et al. is not a proper reference and respectfully asks the Examiner to withdraw his objection to claims 32 and 36 based on this reference.

Applicant further submits that even if the Examiner were to locate an earlier reference that utilizes TENS to obtain a three-dimensional bite registration in a neutral centric position, unless the reference is directed to treatment of sleep apnea, there is no motive to combine references. Thus, such an earlier reference would not pertain to the claimed invention as a whole and can not be properly used to support an obvious rejection under MPEP §2141.02.

For the above mentioned reasons, Applicant believes claims 32, 36, 40 and 41 avoid the prior art cited by the Examiner and are in a condition for allowance.

### **CONCLUSION**

For the reasons set forth above, Applicant believes the pending claims are in a condition for allowance.

Respectfully submitted,

Dated: June 23, 2006

/sdc/

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